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SERVICE PROCEDURE C.A.T.S FUNCTIONAL CHECK

Purpose: This procedure provides instructions for completing a functional check of a C.A.T.S device.

Tools: 6609621 AT1 reference washing chamber

Silicone tubing

Machine Preparation

Connect the CATS device to the AC power source.

Press the <I> switch on the front panel to power up the machine.

NOTE: Should the internal battery be completely discharged, turn the machine on by using the override switch at the rear of the machine.

- The machine will display a self-test, then the date, time, machine description, program selected, and software version.
- Press the <Select Program> switch to advance to the program selection screen.
- Select the Quality Wash program by pressing the <↓> switch until the Quality Wash is highlighted.
- Press the <Enter> switch to select this program and return to the date/time screen.
- Date or time can be corrected by pressing the <Continue> switch to advance to the Set Installation screen. Press the <Option> switch. The key selections will change. Press the <Service Option> switch. Press the <Clock Date> switch and use the appropriate switches to correct the date and time. Press the <Enter> switch when the correct date and time are displayed and return to the Set Installation screen.
- From the Set Installation screen, press the <Open Centrif.Lid> switch. The centrifugal lid will pop open.

Note: The centrifuge lid must be closed before the <Open Centrif.Lid> switch option will be available.

- Locate the centrifuge rotor assembly hood. Confirm the hood locking pins are in the locked (down) position.
- Load the AT1 reference washing chamber into the rotor assembly.
- Press the <Lock Chamber> switch to lock the AT1 reference washing chamber into the rotor. Once the
 machine confirms the chamber is locked, the <Lock Chamber> key changes to <Uniock Chamber> and
 the <Prime> key becomes available.

Pump Loading

- Confirm the pump loading function works properly. Press the <Load Pumps> switch and confirm all
 three pumps rotate no more than one (1) revolution and stop in the segment load position.
- Insert the special silicone tubing into the Saline Fluid and Shed Blood pump detectors to simulate fluid. Position the tubing so that it does not interfere with the centrifuge door closure, or the rotation of any of the pumps.
- Close the centrifuge door and confirm the door latches. The <Open Centrif.Lld> switch is now available.
- Press the <Option> switch, the switch selections will change. Press the <No Prime> switch and the selections change. After a short delay the <Start> switch is displayed.

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Interface Recognition

Press the <Start> switch and confirm that:

the centrifuge starts spinning;

all three pumps start spinning;

centrifuge spins at 2000 rpm while the pumps are spinning; (250)

Shed Blood flow gradually slows down but never stops; PRC, Shed Blood, and Saline volumes are counting up.

When the front panel timer indicates approximately 3 minutes, press the <↑↓> switch. The display will change to show the pump set flow rates.

PRC Flow Adjust

Press the <-> switch repeatedly to change the PRC set flow to 20 ml/min. Press the <Enter> switch and confirm that:

the display changes to show actual flows and volumes:

saline flow reduces;

centrifuge speed slows to 1500 rpm.(2050 - 2200)

- When the front panel timer indicates approximately 6 minutes, press the <↑↓> switch. The display will change to show the pump set flow rates.
- Press the <+> switch repeatedly to change the PRC flow to 45 ml/min. Press the <Enter> switch and confirm that:

the display changes to show actual flows and volumes;

saline flow increases:

centrifuge speed increases to 2250 rpm (720)

- When the front panel timer indicates approximately 9 minutes, press the <Stop> switch. The switch selections change.
- The centrifugal speed should slow to 1400 rpm. (۱۹۰۰)
- After a short delay, the centrifuge should stop.

Save Final PRC

- Once the centrifuge has stopped, press the <Option> switch. The switch selections change.
- Press the <Save Final PRC> switch. The switch selections change again.
- Press the <Save Final PRC> switch again and confirm that:

the centrifuge starts spinning;

PRC pump spins;

saline pump spins:

Shed Blood pump does NOT spin.

- When the Save PRC program finishes, a "Failure: PRC Flow" message is displayed and the program will stop.
- Confirm that the FAILURE: PRC Flow message is displayed along with the total flow volumes.
- Press the <Mute> switch.
- Press the <Option> switch.
- Press the <Reset Program> switch.
- Press the <Clear Program> switch.
- The machine will display C.A.T.S and then the date, time, machine description, program selected, and software version.

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Emergency Wash

- Press the <Select Program> switch. Emergency Wash should be highlighted.
- Press the <Enter> switch.
- The date, time, machine description, program selected, and software version will be displayed.
- Press the <Continue> switch.
- Press the <Lock Chamber> switch to lock the AT1 reference washing chamber into the rotor. When the
 machine confirms the chamber is locked, the <Lock Chamber> key changes to <Unlock Chamber> and
 the <Prime> key becomes available.
- Press the <Option> switch, the switch selections will change. Press the <No Prime> switch and the selections change. After a short delay the <Start> switch is displayed.
- Press the <Start> switch.

(3700)

- After a short delay, the centrifuge should spin at 2350 rpm and all three pumps should start rotating. The Shed Blood pump speed should increase.
- When the front panel timer indicates approximately 3 minutes, press the <Stop> switch. The centrifuge should slow to 1400 rpm and, after a short delay, should stop.
- Press the <Option> switch, then the <Reset Program> switch.
- Press the <Clear Program> switch.
- The machine will display C.A.T.S and then the date, time, machine description, program selected, and software version

The Functional Check is now complete.

Remove the AT1 reference washing chamber and the silicone tubing.

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See ECO for Approval Signatures.